

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE  
 in its capacity as elected Office

<b>Date of mailing</b> (day month year) 25 January 2001 (25.01.01)	
<b>International application No.</b> PCT/GB00/02641	<b>Applicant's or agent's file reference</b> P006424WOCTH
<b>International filing date</b> (day month year) 15 June 2000 (15.06.00)	<b>Priority date</b> (day month year) 17 June 1999 (17.06.99)
<b>Applicant</b> DONALDSON, Iain, Alasdair et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
 22 November 2000 (22.11.00)

☐ in a notice effecting later election filed with the International Bureau on:  
 \_\_\_\_\_

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. 041 22 740 14 45	Authorized officer S. Mafla Telephone No. 041 22 365 35 37
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## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>P006424WOCTH</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/GB 00/ 02641</b>	International filing date (day/month/year) <b>15/06/2000</b>	(Earliest) Priority Date (day/month/year) <b>17/06/1999</b>
Applicant <b>DANISCO A/S</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☒ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☒ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

RICE SUCROSE SYNTHASE PROMOTER

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

# INTERNATIONAL SEARCH REPORT

Int'l Application No

PCT/GB 00/02641

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/54 C12N9/10 C12N15/82 A01H5/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, CHEM ABS Data, STRAND

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>HUANG JU-WEI ET AL: "Complete structures of three rice sucrose synthase isogenes and differential regulation of their expression."  BIOSCIENCE BIOTECHNOLOGY AND BIOCHEMISTRY, vol. 60, no. 2, 1996, pages 233-239,  XP002158594  ISSN: 0916-8451  the whole document</p> <p style="text-align: center;">---</p>	<p>1-7,  10-12,  15-19,  23,26</p>
X	<p>WANG M-B ET AL: "A COMPLETE SEQUENCE OF THE RICE SUCROSE SYNTHASE-1 RSS1 GENE"  PLANT MOLECULAR BIOLOGY, vol. 19, no. 5, 1992, pages 881-885,  XP002158595  ISSN: 0167-4412  the whole document</p> <p style="text-align: center;">---</p> <p style="text-align: center;">-/--</p>	<p>6,7,10,  11,  15-19,26</p>

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*Z\* document member of the same patent family

Date of the actual completion of the international search

26 January 2001

Date of mailing of the international search report

22/02/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel (+31-70) 340-2040, Tx. 31 651 epo nl,  
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Authorized officer

Oderwald, H

# INTERNATIONAL SEARCH REPORT

Int'l Application No

PCT/GB 00/02641

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	<p>DATABASE EMGSS3 'Online!  EMBL Heidelberg, Germany;  AC/ID A0272200,  4 November 1998 (1998-11-04)  WING R A AND DEAN R A: "A BAC end  sequencing framework to sequence the rice  genome"  XP002158597  abstract</p> <p style="text-align: center;">---</p>	<p>1,2,5,7,  10,11,  13,  15-19,  23,26</p>
X	<p>WO 98 10062 A (MONSANTO CO)  12 March 1998 (1998-03-12)</p> <p>the whole document</p> <p style="text-align: center;">---</p>	<p>6,7,10,  11,  15-22,26</p>
X	<p>"Original TA cloning kits, pCR2.1 vector"  INVITROGEN CATALOGUE,  1997, page 7 XP002158596  the whole document</p> <p style="text-align: center;">-----</p>	<p>24</p>

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/02641

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9810062 A	12-03-1998	AU 4173497 A	26-03-1998

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
28 December 2000 (28.12.2000)

PCT

(10) International Publication Number  
**WO 00/78975 A3**

- (51) International Patent Classification<sup>7</sup>: C12N 15/54, 9/10, 15/82, A01H 5/00
- (21) International Application Number: PCT/GB00/02641
- (22) International Filing Date: 15 June 2000 (15.06.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
9914210.1 17 June 1999 (17.06.1999) GB
- (71) Applicant (for all designated States except US):  
DANISCO A/S [DK/DK]; Langebrogade 1, P.O. Box 17,  
DK-1001 Copenhagen K (DK).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): DONALDSON,  
Iain, Alasdair [GB/DK]; Dalgas Have 27, 1 TV, DK-2000  
Frederiksberg (DK). RASMUSSEN, Thomas, Bruun  
[DK/DK]; Gormsvej 10, DK-4900 Nakskov (DK).
- (74) Agents: HARDING, Charles, Thomas et al.; D Young &  
Co., 21 New Fetter Lane, London EC4A 1DA (GB).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE,  
DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU,  
ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS,  
LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO,  
NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR,  
TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian  
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European  
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,  
IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG,  
CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:  
— With international search report.
- (88) Date of publication of the international search report:  
31 May 2001
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: RICE SUCROSE SYNTHASE PROMOTER

(57) Abstract: A promoter is described. The promoter comprises a nucleotide sequence corresponding to that shown as SEQ ID No. 1 or a variant, homologue or derivative thereof.

WO 00/78975 A3

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
28 December 2000 (28.12.2000)

PCT

(10) International Publication Number  
**WO 00/78975 A2**

- (51) International Patent Classification<sup>7</sup>: C12N 15/54, 9/10, 15/82, A01H 5/00
- (21) International Application Number: PCT/GB00/02641
- (22) International Filing Date: 15 June 2000 (15.06.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
9914210.1 17 June 1999 (17.06.1999) GB
- (71) Applicant (for all designated States except US):  
DANISCO A/S [DK/DK]; Langebrogade 1, P.O. Box 17,  
DK-1001 Copenhagen K (DK).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): DONALDSON,  
Iain, Alasdair [GB/DK]; Dalgas Have 27, 1 TV, DK-2000  
Frederiksberg (DK). RASMUSSEN, Thomas, Bruun  
[DK/DK]; Gormsvej 10, DK-4900 Nakskov (DK).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE,  
DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU,  
ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS,  
LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO,  
NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR,  
TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian  
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European  
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,  
IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG,  
CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— Without international search report and to be republished  
upon receipt of that report.

For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

WO 00/78975 A2

(54) Title: PROMOTER

(57) Abstract: A promoter is described. The promoter comprises a nucleotide sequence corresponding to that shown as SEQ ID No. 1 or a variant, homologue or derivative thereof.

## PATENT COOPERATION TREATY

## PCT

REC'D 14 SEP 2001

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)


Applicant's or agent's file reference P006424WOCTH		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/02641	International filing date (day/month/year) 15/06/2000	Priority date (day/month/year) 17/06/1999	
International Patent Classification (IPC) or national classification and IPC C12N15/54			
Applicant DANISCO A/S			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
  - ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  22/11/2000	Date of completion of this report  12.09.2001
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Mueller, F  Telephone No. +49 89 2399 7722





# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/02641

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, pages:**

1-108 as originally filed

**Claims, No.:**

1-26 as originally filed

**Drawings, sheets:**

1/27-27/27 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/02641

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims	3,4,8-14,23,25
	No:	Claims	1,2,5,6,7,15-22,24,26
Inventive step (IS)	Yes:	Claims	3,4,8-14,23,25
	No:	Claims	1,2,5,6,7,15-22,24,26
Industrial applicability (IA)	Yes:	Claims	1-26
	No:	Claims	

2. Citations and explanations  
**see separate sheet**

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB00/02641

**Re Item I**

**Basis of the opinion**

Sequence listings filed, 4 pages, Seq IDs.: 1-6, with the letter of 11.09.2000, are filed after the filling date of the application and do not form part of the description and will not be annexed to this communication/report (Rule 13ter(f) PCT).

**Re Item V**

**Reasoned statement under Article 35 (2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: WO 98 10062 A (MONSANTO CO) 12 March 1998 (1998-03-12)
- D2: 'Original TA cloning kits, pCR2.1 vector' INVITROGEN CATALOGUE, 1997, page 7
- D3: DATABASE EMGSS3 [Online] EMBL Heidelberg, Germany; AC/ID AQ272200, 4 November 1998 (1998-11-04) WING R A AND DEAN R A: 'A BAC end sequencing framework to sequence the rice genome'

1. The subject-matter of independent claim 1 is not novel (Article 33 (2) PCT). D3 describes a sequence which is partially complementary to Seq Id 1 of the present application. The sequence of D3 has a homology of 90% between nucleotides 1-112 of the claimed Seq Id 1.

The same holds true for independent claim 2 and dependent claim 5.

2. The subject-matter of independent claims 6 and 26 is not novel (Article 33 (2) PCT). D1 describes the rice (which is considered as genus *Oryza*) glutelin-1 promoter (p.4, l.3-14) which is used for expressing foreign mammalian genes in the endosperm (p.23, l.20-22, figures 4 and 5 and p.24, l.26-33 and claims). All technical features of claims 6 and 26 are disclosed in D1, the requirements of novelty are thus not fulfilled.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB00/02641

- 2.1 The same holds true for thereon dependent claim 7.

D1 describes the glutelin-1 promoter which is operably linked to the sequences of the light and heavy chains of BR96 (see figures 4 and 5 and e.g. p.9, l. 10-12).

The BR96 sequences are considered to represent a NOI.

3. The subject-matter of independent claims 15,16,17 and 18 is not novel (Article 33 (2) PCT).

D1 describes a construct which is suitable for the expression of mammalian genes in endosperm by using a glutelin-1 promoter expression vector. Thus novelty of claim 15 can not be acknowledged.

The same holds true for independent claims 16 and 17.

Furthermore D1 refers to a transformed host cell (maize) containing a rice-glutelin promoter expression construct (see claims 8-10). The requirements of novelty for claim 18 are therefore not fulfilled (Article 33 (2) PCT).

The same holds true for thereon dependent claim 19.

4. The subject-matter of independent claims 20 and 22 is not novel (Article 33 (2) PCT).

D1 describes a method for preparing foreign gene products (p.20,l.23-p.21,l.26) from transformed maize plants (p.18,l.26- p.20,l.23) by using an glutelin-1 promoter expression construct (see item also 2). All technical features of independent claims 20 and 22 are therefore disclosed in D1.

The same holds true for thereon dependent claim 21.

5. The subject-matter of independent claim 24 is not novel (Article 33 (2) PCT).

D2 refers to a commercially available vector construct which is used in the present application (see e.g. on page 78, l.18-PCR2.1). Novelty can therefore not be acknowledged.

6. The subject-matter of claims 3,4,8-14,23 and 25 is novel (Article 33 (2) PCT).

The promoter sequence presented as Seq Id 1 in the present application is novel.

Furthermore the use of seq id 2 (an intron sequence) and seq id 5 (an exon

sequence) within the claimed promoter expression construct used for recombinant expression in plant cells is novel.

- 6.1 The subject-matter of claims 3,4,8-14,23 and 25 is inventive (Article 33 (3) PCT). The closest prior art is considered to be D1. D1 describes an glutelin-promoter containing expression vector which is suitable for the expression of mammalian genes in maize (see item 2 and 4). The problem to be solved by the present application may therefore be regarded as to provide a different promoter which allows endosperm expression in plants. A solution therefore is provided in the present application by the use of RSus3 promoter sequence of rice (seq Id 1). In addition it was found that the combination of Seq Id 2 (an intron sequences ) and Seq Id 5 (an exon sequence) with that Seq Id 1 is suitable for modulating (to elevate) the expression levels of a NOI (see p.11,l.7-12). As there is no indication in the prior art to use the RSus 3 promoter alone or in combination with the specific intron and exon sequences for allowing expression of mammalian genes in plants, an inventive step can be acknowledged (Article 33 (3) PCT).
7. The further cited X-documents in the International Search Report; Huang et al., describing genomic sequences of the rice sucrose synthase and which is silent over promoter sequences and vector constructs for recombinant expression and Wang et al., describing the rice RSs1 gene; are not considered to be relevant in respect to novelty or inventive step.

### **Re Item VII**

#### **Certain defects in the international application**

1. Pages 16/27,17/27 and 18/27 (figures 16a-16f) of the drawings are only partially readable and therefore do not fulfil the requirements of Rule 11 (6)(c) PCT. When amendments to the drawings are made greatest care should be taken not contravening the requirements of Article 34 (2)(b) PCT.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No PCT/GB00/02641

2. The vague and imprecise statement "...without departing from the scope and spirit.." in the description on page 105, lines 9-16, implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also PCT Guidelines, C-III, 4.3).
3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in document D1 is not mentioned in the description, nor is this document identified therein.
4. The application should be self-contained. Therefore the term "incorporated by reference" e.g. on page 30, line 29 and on page 105, line 8 does not fulfil the requirements of the PCT-Guidelines C-II,4.17.
5. The reference to non-published patent applications (e.g. on p.29, l.16) should be changed to published application numbers throughout the application (PCT Guidelines,C-II.4.17).

**Re Item VIII**

**Certain observations on the international application**

1. Claims 1,2,8,9,13 are not clear (Article 6 PCT).  
The terms "variant, homologue, fragment or derivative thereof" renders the subject-matter for which protection is sought unclear. The technical features of the claimed nucleotide sequences therefore should be defined by the definitions out of the description on page 25, line 9- page 26, l.22.
2. The terms "comprising" and "having" have the same meaning and therefore renders the set of claims 1 and 2 unclear (Article 6 PCT). It seems that the term "having" should be replaced by "consisting".
3. It is not clear from the wording of claims 1,2,6,23 and 26 if the promoter is an isolated promoter. Thus the requirements of Article 6 PCT are not fulfilled.
4. Claims 10 and 11 are not clear (Article 6 PCT).

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/GB00/02641

The promoter comprising sequences should be identified by sequences identification numbers.

5. The term "comprising the invention" does not describe any technical features and therefore render claims 16-18 unclear (Article 6 PCT).
6. Claim 23 is not clear (Article 6 PCT).  
No technical features for isolating the promoter sequence from the deposited microorganism are provided.
7. Claim 24 is not clear (Article 6 PCT).  
The technical features of the plasmids are fully undefined.
8. Claim 26 does not meet the requirements of Article 6 PCT. The term "substantially" render the technical features of the promoter unclear.